

REMARKS

This is a full and timely response to the Office Action mailed July 31, 2006, submitted concurrently with a two month Extension of Time to extend the due date for response to December 31, 2006.

By this Amendment, claims 1, 2, 7, 8, 11, 12, 16, 17, 19 and 21 have been amended to address the rejection under 35 U.S.C. §112, second paragraph. Support for the claim amendments can be found variously throughout the specification, see for example, the original claims. Thus, claims 1-5 and 7-21 remain pending in this application.

In view of this amendment and the following remarks, Applicant believes that all pending claims are in condition for allowance. Reexamination and reconsideration in light of the above claims and the following remarks is respectfully requested.

Objection to the Specification

The specification is objected to for failing to properly cite the application priority data. Applicant has effected amendments to the specification to overcome this objection. Thus, withdrawal of this objection is respectfully requested.

Rejection under 35 U.S.C. §112

Claims 1-5 and 7-21 are rejected under 35 U.S.C. §112, second paragraph, for alleged indefiniteness. The Examiner has rejected the phrase "*which is to form*" stating that the phrase denotes a futuristic event. Although Applicant respectfully disagrees with the Examiner, in the interest of expediting the prosecution of the present application, Applicant has replaced the phrase "*which is to form*" in the claims with the phrase *--has or having a property of forming--* which Applicant believes overcome this rejection.

Applicant wishes to note that the claims have been amended to clarify that the functional group of the metal complex has a **property** of forming a covalent bond with the amino group of the N-terminal which does not mean that there is an actual covalent bond between the metal complex and the amino group of the N-terminal.

With regard to the term "*derivative*", Applicant has amended claims 16 and 21 to clarify that the derivative is a derivative of said metal complex. Although the Examiner might argue that such amendment does not clarify the similarity between the derivative and the base

compound, Applicant believe that in view of the other limitations in the claims (i.e. “*reacting a metal complex which comprises a functional group which has a property of forming a covalent bond with an amino group of an N-terminal amino acid residue of protein or peptide or with a carboxyl group of a C-terminal amino acid residue of protein or peptide, with a protein or peptide (A) of which the amino acid sequence is to be determined, to form a derivative (B) of said metal complex where the covalent bond of the functional group of the metal complex with the amino group of the N-terminal amino acid residue of the protein or peptide (A) or with the carboxyl group of the C-terminal amino acid residue of protein or peptide is formed*”), the metes and bounds of the term “derivative” is clear when read in context.

In addition, Applicant believes that the phrase “*a derivative of said metal complex*” is not indefinite in terms of its scope. Applicant believes that the Examiner might be rejecting the phrase “*a derivative of said metal complex*” as indefinite due to its breadth. However, under the phrase “*a derivative of said metal complex*” as indefinite due to its breadth. However, under U.S. case law, the breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if Applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph.

Thus, in view of the amendments to the claims, withdrawal of this rejection is respectfully requested.

Rejection under 35 U.S.C. §103

Claims 1-5 and 7-21 are rejected under 35 U.S.C. §103 in view of previously cited references, Garipey (WO 93/23425) in view of Anderson et al. (U.S. Patent No. 5,439,829) and further in view of newly cited reference, Liao et al. (Journal of American Society of Mass Spectrometry, Volume 8, pages 501-509, 1997). Applicant respectfully traverses this rejection.

To establish a *prima facie* case of obviousness, the following three criteria must be satisfied. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations. Here, in this case, based on Applicant's

review of the cited references and the Examiner's comments, Applicant submits that the above criterias have not been satisfied.

Based on Applicants' review of the Examiner's comments, Applicants do not believe that the Examiner has sufficiently established the motivation to modify the composition of Gariepy in accordance with the teachings of Anderson et al. and Liao et al. The Examiner has made only conclusory statements that "*an artisan of ordinary skill, at the time that said invention was made, would be motivated to combine the teachings of each one of the cited references to develop a composition, reagent and a method to determine the amino acid sequence of a peptide/protein, applying said composition/reagent as discussed above.*" In other words, the Examiner has cited the present invention as the source of motivation to combine the cited references since based on Applicants' review of the cited references, Applicants believe that no specific motivation is disclosed in Gariepy, Anderson et al. and Liao et al.

Under U.S. practice, to establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the Examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. *In re Geiger*, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987)

The Federal Circuit has repeatedly warned that the requisite motivation must come from the prior art and not from Applicant's specification. *In re Dow Chem. Co.*, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531-32 (Fed. Cir. 1988) ("*[t]here must be a reason or suggestion in the art for selecting the procedure used, other than the knowledge learned from the Applicant's disclosure.*"). Using the Applicant's disclosure as a blueprint to reconstruct the claimed invention from isolated pieces of the prior art contravene the statutory mandate of section 103 of judging obviousness at the point in time when the invention was made. In this case, the Examiner has not cited any teachings or suggestions in Gariepy, Anderson et al. and Liao et al. which would lead one skilled in the art to motify or combine these references to arrive at the invention. Hence, since the Examiner has cited the present invention as the source of motivation to combine the

cited references, Applicants believe that the Examiner's rejection under 35 U.S.C. §103(a) cannot be sustained under U.S. practice and should be withdrawn.

Furthermore, Applicants also submit that the Examiner has not established a *prima facie* case that there is a reasonable expectation of success. Under U.S. practice, to establish a *prima facie* case of obviousness, a reasonable expectation of success is necessary. *In re Clinton*, 527 F.2d 1226, 1228, 188 U.S.P.Q. 365, 367 (C.C.P.A. 1976). In this case, the Examiner has made only a conclusory statement that "[F]rom the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention". However, the Examiner has not explained how the different teachings of the cited references would lead one skilled in the art to conclude that there would have been a reasonable expectation of success. In moving from the prior art to the claimed invention, one cannot base a determination of obviousness on what the skilled person might try or find obvious to try. Rather, in evaluating obviousness, one must look to see if "*the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art.*" It should be noted that "[B]oth the suggestion and the expectation of success must be founded in the prior art, not in the Applicant's disclosure." *In re Dow Chem.*, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1532 (Fed. Cir. 1988).

The Examiner has combined the different teachings of Gariepy, Anderson et al. and Liao et al. with no explanation as to why one skilled in the art would be motivated to combine such teachings or why such a combination would have a reasonable expectation of success. The teachings of Gariepy, Anderson et al. and Liao et al. gives either no indication of which parameters are critical or no direction as to which of many possible choices is likely to be successful especially since the references do not disclose any particular purpose or advantage which would lead one skilled in the art to combine the cited references to arrive at the present invention.

The present invention is directed to the development of a rapid and highly-sensitive method for determining the amino acid sequence of a protein or peptide through mass spectrometry using a novel metal complex having a functional group which has a property of forming a covalent bond with an amino group (of an N-terminal amino acid residue of protein or

peptide) or with a carboxyl group (of a C-terminal amino acid residue of protein or peptide) such that the covalent bond is not cleaved in a stage of ionization in mass spectrometry.

The combination of the prior art cited by the Examiner does not recognize this "result-effective" capability of the claimed invention parameters (i.e. novel metal complex having **a functional group which has a property of forming a covalent bond** with an amino group or a carboxyl group of an amino acid residue of protein or peptide, and **covalent bond is not cleaved in a stage of ionization in mass spectrometry**). Thus, no reasonable expectation of success would exist since the cited references provide no guidance on the parameter to optimize which would yield the desired result (i.e. *a rapid and highly-sensitive method for determining the amino acid sequence of a protein or peptide through mass spectrometry*). *In re Antonie*, 559 F.2d 618, 195 U.S.P.Q. 6 (C.C.P.A. 1977).

Thus, for these reasons, withdraw of this rejection is respectfully requested.

Application No. 10/614,324
Inventors: Norikazu Ueyama et al.
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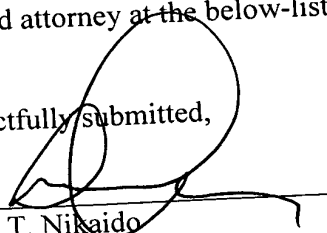
Docket No.: OKA-0209
Group Art Unit: 1655
Examiner: Kailash C. Srivastava

CONCLUSION

For the foregoing reasons, all the claims now pending in the present application are believed to be clearly patentable over the outstanding rejections. Accordingly, favorable reconsideration of the claims in light of the above remarks is courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the below-listed number.

Dated: December 29, 2006

Respectfully submitted,

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